

REMARKS

Claims 91-126 and 150-161 are pending. Claims 91, 94-114, 116-122, 123, 124, 150-156, and 157-161 have been amended. Claims 92-93, 95, and 115 have been cancelled. Claims 130-149 have been withdrawn due to a previous Restriction Requirement. New Claims 162 and 163 have been added. Support for the new claims is found on page 7 of the Specification.

The amendments have been made to place the claims in better form for examination and to further obviate the 35 U.S.C. § 112 and 103(a) rejections as set forth in the Office Action dated June 1, 2009. It is believed that none of these amendments constitute new matter. Withdrawal of these rejections is respectfully requested.

Claim Rejection-35 U.S.C. § 112, second paragraph

The Examiner has rejected Claim 91 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically the Examiner states that there is no antecedent basis in Claim 91 for the “oil emulsion” in line 7. Claim 91 has been amended and in so doing “oil emulsion” in line 7 of the claim has been removed. Withdrawal of this rejection is respectfully requested.

Claim Rejection-35 U.S.C. § 112, first paragraph

The Examiner has rejected to Claims 91-125 and 150-161 under 35 U.S.C. 112, first paragraph, because the Office Action states that the specification does not reasonably provide enablement for a “solution” that is an oil in water emulsion. Claims 91, 94-121, 150-156 and 158-161 recite a product comprising an oil-in water emulsion. Support for this amendment may be found in Examples 2 and 3 described in the specification as well as on page 10, lns 23-25 of the specification. Withdrawal of this rejection is respectfully requested.

Claim Rejection – 35 U.S.C. §103 – Nakajima as further evidenced by Firestone

The Examiner has rejected claims 91-95, 98-101, 104-117, 122-123 and 125 under 35 U.S.C. § 103(a) as being unpatentable over Nakajima (US Patent 7,029,719) as further evidenced by Firestone (Physical and Chemical Characteristics of Oils, Fats and Waxes; AOCS Press.

US Application No. 10/518,957
Final Office Action Mailed: June 1, 2009

1999; pgs 90, 91, 94 and 95). Applicants respectfully traverse this rejection in light of the amendments and arguments presented herein.

The Office Action states that Nakajima discloses a mayonnaise-like food that is oil in water emulsion, emulsifiers included at a level of up to 5%, stabilizers are included in the composition as thickening polysaccharides and soybean and sesame seed oil as oil sources. The Office Action does state that Nakajima differs from the claims of the present invention in the recitation of polyunsaturated oil and in the recitation that the composition is not heat treated. In addition, the Office Action notes that all of the weight ratios of the claims of the present invention are not mentioned in Nakajima.

The Office Action states that it would have been obvious to omit heating the mayonnaise of Nakajima and that one of ordinary skill in the art would be expected to optimize the amount of each ingredient according to the extent of calories and according to the extent of stability desired in the product.

Claim 91 recites an oil component from a microbial source (support found on page 5 of the Specification) comprising a polyunsaturated fatty acid (PUFA) selected from arachidonic acid, eicosapentaenoic acid, docosapentaenoic acid, docosahexaenoic acid and mixtures thereof. Nakajima does not teach or suggest an oil component from a microbial source nor the longer chain PUFAs as claimed by the present invention. In addition, Firestone also does not disclose or suggest oils from a microbial source but oils from plants such as soybean and sesame oils which are composed of polyunsaturated fatty acids with less than 20 carbons and thus does not make up for the deficiencies of Nakajima.

In order to support a *prima facie* case of obviousness, a combination of references must teach each and every one of the claimed elements in addition to showing a motivation to combine and a reasonable expectation of success. Since the combination of Nakajima and Firestone does not teach all of the elements of independent claim 91, nor its dependent claims, withdrawal of this rejection is respectfully requested.

Claim Rejection – 35 U.S.C. §103 – Traska as further evidenced by Firestone

The Examiner has rejected Claims 91-95, 98-120, 122-125, 150-161 under 35 U.S.C. 103(a) as being unpatentable over Traska (US Patent 6,423,363) as further evidenced by

Firestone. The Office Action states that Traska discloses an aqueous dispersion of plant sterols and lipids and that the dispersion is contemplated for use in spreads, dressings, beverages and dairy products. In addition, the surfactants used in the product are disclosed and are the same as those claimed in the present invention (as well as the level of surfactant). Also, the Office Action contends that Traska discloses emulsion stabilizers, vitamins, preservatives, low pH products, and a water continuous spread, which the Office Action refers to as an “oil in water emulsion”. The Office Action does state that there is no restriction placed on the particular fat or oil used in the product and that no heat treatments are mentioned. In addition, the Office Action states that the claims of the present invention differ from Traska in the recitation of an oil component that is a polyunsaturated fatty acid.

The Office Action contends that it would have been obvious to use the aqueous dispersion of Traska as the emulsion of the claims in light of the Firestone evidence (fatty acid content of soybean and sesame oil) concerning the presence of unsaturated fatty acids in soybean oil. The Office Action also asserts that it would have been obvious to modify the ratios of ingredients in Traska. Applicants respectfully traverse this rejection in light of the amendments and arguments presented herein.

Claims 91 and 150 recite an oil component from a microbial source comprising a polyunsaturated fatty acid selected from arachidonic acid, eicosapentaenoic acid, docosapentaenoic acid, docosahexaenoic acid and mixtures thereof. Traska does not teach or suggest an oil component from a microbial source comprising a polyunsaturated fatty acid selected from arachidonic acid, eicosapentaenoic acid, docosapentaenoic acid, docosahexaenoic acid and mixtures. In addition, Firestone also does not disclose or suggest oils from a microbial source but oils from plants such as soybean and sesame oils which are composed of polyunsaturated fatty acids with less than 20 carbons (and thus, do not include arachidonic acid, eicosapentaenoic acid, docosapentaenoic acid, docosahexaenoic acid) and thus, does not make up the deficiencies of Traska.

In order to support a *prima facie* case of obviousness, cited references must teach each and every one of the claimed elements in addition to showing a motivation to combine and a reasonable expectation of success. Since Traska, as evidenced by Firestone does not teach all of

the elements of independent claims 91 and 150, withdrawal of this rejection is respectfully requested.

Claim Rejection – 35 U.S.C. §103 – Traska as further evidenced by Firestone and in further view of Kohn or Kyle

The Examiner has rejected Claims 96, 97 and 121 under 35 U.S.C. 103(a) as being unpatentable over Traska as further evidenced by Firestone as applied to Claims 91-95, 98-120, 122-126 and 150-157, and further in view of Kohn (US Patent Publication 2005/0129739) or Kyle (US Patent 5,658,767). The Office Action states that oils from microorganisms and genetically modified plants are known in the art (Kohn and Kyle) and thus it would have been obvious to utilize the oils of Kohn and Kyle in order to enhance the nutritive quality of the food.

As noted above, the composition of Traska is fundamentally different from the claimed product comprising an oil-in-water emulsion because Traska does not teach or suggest an oil component from a microbial source comprising a polyunsaturated fatty acid selected from arachidonic acid, eicosapentaenoic acid, docosapentaenoic acid, docosahexaenoic acid and mixtures thereof. In addition, while Kohn et al. discloses polar-rich fractions (production and use) containing polyunsaturated fatty acids from microorganisms, genetically modified seeds and marine organisms and Kyle discloses the production of arachidonic acid containing oils that are substantially free of eicosapentaneoic acid, neither reference discloses a product having an oil-in-water emulsion as claimed.

In addition, there is no motivation to combine Traska with either Kohn or Kyle to arrive at a product comprising an oil-in-water emulsion as claimed. Since Kyle is concerned with arachidonic acid containing oils for use in infant formula that are substantially **free** of eicosapentaneoic acid, one of skill in the art would not be motivated to use the oil described by Kyle in combination with the oil-in-water emulsion of Traska to arrive at the claimed product comprising the oil-in-water emulsion of the present invention which can include mixtures of DHA, DPA, EPA and ARA. Kyle states that “. . . it would be desirable to be able to provide ARA without also providing additional EPA” (column 1 lines 64-65). In addition, the Office Action has provided no motivation to combine the oil-in-water emulsion of Traska (high melting point lipids) with the ARA containing oil (low melting point PUFA) of Kyle. Traska is

principally concerned with administration of phytosterols, and Kyle is principally concerned with the production of ARA for incorporation in infant formula. While the Office Action states that it would have been obvious to utilize the oil of Kyle in order to enhance the nutritive quality of the composition, there is no teaching in the references to make such a combination, and no apparent reason that a skilled person would substitute the oil sources of Kyle for those of Traska.

Therefore, it appears that the Office has used the present disclosure to prepare a hindsight-based reconstruction of the claimed invention.

Kohn discloses a method for producing a polar lipid-rich fraction that is enriched with EPA, DHA, DPA and ARA (which are liquid at room temperature) and that is in a polar form, such as in a phospholipid form, whereas Traska discloses high melting, water insoluble sterols and other lipids having a melting point within the range of 75-200°C (Traska col 5, lns 41-43). Thus there is no motivation for one of skill in the art to combine the oil-in-water emulsion of Traska (high melting point lipids) with the polar lipid-rich fractions of Kohn, to arrive at the claimed product comprising the oil-in-water emulsion of the present invention. In addition, Kohn is limited to a polar-rich fraction and discloses that the phospholipid form of the PUFA(s) functions itself as an emulsifier ([0034]). Kohn does not teach or suggest the use of another emulsifier and emulsion stabilizer and therefore one of skill in the art would not be motivated to combine the teachings of Kohn with the teachings of Traska to arrive at the claimed product comprising the oil-in-water emulsion of the present invention. While the Office Action states that it would have been obvious to utilize the oil of Kohn in order to enhance the nutritive quality of the composition, there is no teaching in the references to make such a combination, and no apparent reason that a skilled person would substitute the oil sources of Kohn for those of Traska. Again, it appears that the Office has used the present disclosure to prepare a hindsight-based reconstruction of the claimed invention.

Since there is no motivation to combine the teachings of Traska, Firestone, Kohn or Kyle to arrive at the claimed product comprising an oil-in water emulsion, one of skill in the art would not be motivated to optimize the relative amounts of the components as asserted by the Office Action. Additionally, no reasoning or evidence is provided explaining why one skilled in the art would have been motivated to modify the teachings of Traska, Kohn or Kyle. “Rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some

US Application No. 10/518,957
Final Office Action Mailed: June 1, 2009

articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1396, quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). According to the *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526 (October 10, 2007), the Examiner must provide some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. In the present case, no explanation or support has been provided to show that one skilled in the art would have been motivated to modify the teachings of Traska, Kohn or Kyle to arrive at the product comprising an oil-in water emulsion of the present invention.

For the foregoing reasons, withdrawal of the rejection of Claims 96, 97 and 121 is respectfully requested.

Closing Remarks

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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